

REMARKS

Reconsideration and allowance of this application are respectfully requested in light of the foregoing amendments and the following remarks.

Claim Status

Claims 1 and 12 were amended and claims 17-18 were added. Claim 13 was cancelled. Claims 1-12 and 14-18 are pending. No new matter was added. Basis for new claims 17-18 may be found in the specification in the paragraph bridging pages 6-7, in the paragraph bridging pages 7-8 and at the end of the 2nd paragraph on page 8.

§102/103 Claim Rejections

Claims 1, 4, 8-12, 14 and 16 stand rejected under 35 U.S.C. §102(e) as being anticipated by or, in the alternative, under 35 U.S.C §103(a) as obvious over U.S. Patent Application No. 2004/0045897 (hereinafter Nakabayashi) as evidenced by Developments in Medical Polymers for Biomaterials Applications, KATZ (hereinafter Katz). Applicant traverses.

As stated in the previous office action, to anticipate a claim under 35 U.S.C. §102(b), a single source must contain all of the elements of the claim. *See Hybritech Inc. v. Monoclonal*

Antibodies, Inc., 802 F.2d 1367, 1379, 231 USPQ 81, 90 (Fed. Cir. 1986); *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1574, 224 USPQ 409, 411 (Fed. Cir. 1984); *In re Marshall*, 578 F.2d 301, 304, 198 USPQ 344, 346 (C.C.P.A. 1978). Missing elements may not be supplied by the knowledge of one skilled in the art or the disclosure of another reference. See *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716, 223 USPQ 1264, 1271 (Fed. Cir. 1984). Where a reference discloses less than all of the claimed elements, an Examiner may only rely on 35 U.S.C. §103. See *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 780, 227 USPQ 773, 777 (Fed. Cir. 1985).

The Examiner considered Applicant's arguments regarding claim 1, but did not find them persuasive. Specifically, the Examiner argues that while the zwitterionic compound of Nakabayashi has a zero net charge, the zwitterionic negative charge on the compound renders the application at a minimum obvious and in the alternative anticipatory. The Examiner, however, has overlooked numerous relevant facts. For instance, both amended claim 1 and claim 9 require the employment of a polyelectrolyte with negative fixed charges, but having no positive fixed charges. The increase in separation efficiency of the membranes of the instant invention is realized only when polyelectrolytes having negative fixed charges and having no

positive fixed charges are used. If polyelectrolytes having positive fixed charges are added to the interior filler, the resulting membranes show no increased separation efficiency. (Specification, Page 5, Lines 5-8). The present characterization of the polyelectrolyte required by amended claim 1 clearly excludes the zwitterionic compounds of Nakabayashi which carry both negative and positive groups resulting in a zero net charge.

Another relevant fact ignored by the Examiner is that according to the instant invention, a polyelectrolyte with a negative fixed charge, but having no positive fixed charge is employed. Nakabayashi, however, does not disclose a polyelectrolyte. Those of skill in the art know that "an electrolyte is any substance containing free ions that make the substance electrically conductive." (See enclosed definition of electrolyte from Wikipedia). Looking to Hackh's Chemical Dictionary, an electrolyte is "a substance that dissociates into 2 or more ions, to some extent, in water. Solutions of electrolytes thus conduct the electric current and can be decomposed by it. (See enclosed definition from Hackh's Chemical Dictionary, McGraw-Hill Book Company, Pages 234-35, (1969)). Moreover, looking to the same source, a polyelectrolyte is "a polymer producing large chain-type ions in

solutions, that can carry positive or negative groups along the polymer chain." (emphasis added - Page 533). No where within these passages is it stated that a polyelectrolyte can carry "positive and/or negative groups...". Looking now to the enclosed passages from Fumio Oosawa's textbook on polyelectrolytes, we read that "polyelectrolytes are macromolecules having many ionizable groups. In solution they are dissociated into polyvalent macroions (polyions) and a large number of small ions of opposite charge (counter ions). (Fumio Oosawa: "Polyelectrolytes"; Marcel Dekker, Inc., New York, Page 1 (1971)).

The above definitions are contrasted by the MPC co-polymer or Nakabayashi which is a zwitterion and, as admitted by the Examiner, therefore has zero net charge. Looking to the enclosed printout from Wikipedia, "a zwitterion is a chemical compound that carries a total net charge of zero and is thus electrically neutral, but carries formal charges on different atoms." (See enclosed definition of zwitterion from Wikipedia). Thus, zwitterions carry positive and negative groups. In solution, zwitterions are not dissociated into polyvalent macroions (polyions) and a large number of small ions of opposite charge (counter ions). Both ions are bound to the same molecular backbone, each localized at a different point in the

molecule. Therefore, zwitterions lack the ability to conduct electric current. In summary, a zwitterion is not a polyelectrolyte and therefore is not a polyelectrolyte with negative fixed charges according to claim 1 of the instant invention. Thus, claim 1 of the instant invention is not anticipated by Nakabayashi and should be allowed.

Despite the claim to the contrary by the Examiner, claim 1 of the instant invention is also not obvious over Nakabayashi. Nakabayashi provides no hint or motivation that by using a polyelectrolyte, let alone a polyelectrolyte with negative fixed charges, one may obtain a membrane having improved separation efficiency. Nakabayashi specifically deals with hollow fiber membranes consisting of a copolymer of MPC and other vinyl-polymerizable monomers as additives in a higher concentration on the inside and/or the outside surface of the membrane than the other parts of the membrane. (Nakabayashi, Claim 1) Additionally, Nakabayashi clearly states on Page 4, Paragraph 38 that:

...the hollow fiber membrane can be modified in the present invention by unevenly distributing the MPC copolymer on the membrane surface. Such a hollow fiber membrane can be obtained by a method of causing the MPC copolymer adsorbed on the surface of a previously manufactured hollow fiber membrane, as mentioned above, or by a method of unevenly distributing the MPC copolymer on the membrane surface when the membrane is manufactured.

The membranes of Nakabayashi shall be used for e.g. hemodialysis or blood filtration whereby the membranes are made from a synthetic polymer.

By adding the MPC copolymers, membranes shall be provided with a surface exhibiting only small interaction with biological components and excelling in biocompatibility. (Nakabayashi, Page 2, Paragraph 10). Nakabayashi is absolutely silent concerning separation behavior of the membranes, let alone the separation efficiency of the membranes. A person skilled in the art is left in the dark on how to modify the teachings of Nakabayashi in order to obtain membranes having improved separation efficiency such as those disclosed within the instant invention. Nakabayashi contains neither reason nor motivation for one skilled in the art to alter the process and membranes described therein by using polyelectrolytes with negative fixed charges as an alternative to the MPC copolymers with are zwitterions having zero net charge in order to obtain membranes with improved separation efficiency. Thus, claim 1 of the instant invention is not obvious over Nakabayashi and should be allowed.

Looking now to claim 4 of the instant invention, the meaning behind the Examiner's rejection is difficult to ascertain. On Page 9 in her "Response to Arguments" section, the Examiner refers to Page 5, Paragraph 44 of Nakabayashi. However, in the Applicant's humble opinion, this passage has no relevance with respect to claim 4 of the instant invention. Paragraph 44 of Nakabayashi discloses a process for manufacturing the membranes of Nakabayashi, wherein a headily prepared hollow fiber membrane is after-treated with a solution of the MPC copolymer in a suitable solvent, whereby the solution of the MPC copolymer is caused to come into contact with the membrane surface, thereby causing the MPC copolymer to be absorbed.

This process has nothing in common with claim 4 of the instant invention which depends from claim 1. Specifically, claim 4 relates to a method for production of an integrally asymmetric membrane, wherein during manufacturing of the membrane, a polyelectrolyte with negative fixed charges is introduced into the membrane structure. More specifically, according to amended step c, the first and/or second surface of the shaped spinning solution is brought into contact with a precipitant system, whereby a membrane with a separation layer is formed and whereby this precipitant system contains the

polyelectrolyte with negative fixed charges and wherein according to claim 4 this polyelectrolyte is not soluble in the spinning solution, but instead precipitates in contact with the spinning solution.

Thus, while Paragraph 44 of Nakabayashi related to an after-treatment of a readily prepared membrane, the instant invention related to the addition of a polyelectrolyte during the formation of a membrane.

Looking now to the Examples referred to by the Examiner, and in particular Example 1 of Nakabayashi. There is neither a disclosure that the dissolved interior filler precipitates in contact with the spinning solution, nor is there a disclosure that is occurs as the spun raw material is passed through a water bath. Applicant has no insight as to the Examiner's basis for this interpretation of Nakabayashi. According to Example 1, a spinning solution ("membrane-forming raw material solution") was discharged from spinnerets with an annular orifice. This, the spinning solution is formed into a hollow fiber. In addition to the annular orifice, the spinneret for producing hollow fiber membranes in the center of the annular orifice has an inner opening via which an interior filler ("hollow space inner solution"/"internal coagulate solution") is discharged

simultaneously with the spinning solution. The interior filler both 1) forms the hollow space or lumen of the hollow fiber, and 2) acts as a coagulant for the polymer which is dissolved in the spinning solution, thereby forming e.g. a separating layer. The spun yarns, i.e. the spinning solution in the form of a hollow fiber, together with the interior filler in the lumen, are then immersed in an (outer) coagulation bath located below the spinning nozzles. (See Page 2, Paragraph 15, Lines 1-8 and Pages 4-5, Paragraph 40, Lines 4-13).

Thus, according to the disclosure of Nakabayashi, the membrane forming polymer in the spinning solution coagulates on contact with the interior filler. During the coagulation of the membrane forming polymer, the MPC polymer is entangled with molecular chains of the membrane forming polymer or incorporated into dense structure near the inner surface. Please also see pages 10-12 of the previous Amendment submitted by Applicant concerning Claim 4 of the instant invention. Contrary to the Examiner's assertion to the contrary, there is not disclosure within Nakabayashi of a polymerization.

Regarding the amendment to independent claim 12, Nakabayashi does not disclose a polyelectrolyte with negative fixed charges for the same reasons set forth previously for

claim 1 above. Thus, amended claim 12 of the instant invention is neither anticipated nor obvious over Nakabayashi and should be allowed.

In reference to claims 4, 8-11, 14 and 16, "[I]f an independent claim is not anticipated by prior art, then its dependent claims, which necessarily include the limitations of the independent claim, are not anticipated either. *Kovin Assoc. v. Extech/Exterior Technologies*, 2006 U.S. Dist. LEXIS 63250 (N.D. Ill. 2006), citing *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1296 (Fed. Cir. 2002). Thus, claims 4, 8-11, 14 and 16 are not unpatentable over Nakabayashi and should be allowed.

§103 Claim Rejections

Claims 1-12 and 14-16 stand rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 4,604,208 (hereinafter Chu) in combination with U.S. Patent Application No. 2004/0045897 (hereinafter Nakabayashi). Applicant traverses.

The above comments regarding Nakabayashi and Katz are incorporated herein. It is with all due respect to the Examiner that Applicant expresses the deepest confusion as to the

Examiner dismissing the arguments set forth in the previous office action regarding both the Chu and Nakabayashi references. The Examiner's claim that one skilled in the art would be motivated to combine the teachings of Chu with the teachings of Nakabayashi in order to improve the efficiency of the process disclosed in Chu would in no way achieve the integrally asymmetric membrane with improved separation efficiency as is described in the instant application.

As was clearly stated above, Nakabayashi does not disclose the use of polyelectrolytes having **only** negative fixed charges and **no positive fixed charges**. Instead, Nakabayashi makes use of zwitterions. (Please see the detailed arguments presented above). Additionally, the goal of the instant invention is to provide integral asymmetric membranes having improved separation efficiency. This is contrary to the membranes described by Chu, (i.e. membranes which after having been completely precipitated are provided with a polyelectrolyte) which do not show an improvement in separation efficiency due to the interlocking and entanglement of the polymer chains of the polyelectrolyte with those of the membrane forming polymer being hardly possible. (Specification, Page 15, Paragraph 1). Chu also fails to address any of the aspects of separation characteristics of the membranes. Chu instead discloses membranes aimed at solving the

problem of bacterial breakthrough. (Column 1, Lines 38-61, Column 2, Lines 2-5). Chu also seeks to produce membranes for the removal of fine charged particulates from liquids. (Column 2, Lines 61-66, Column 5, Lines 23-35). In fact, Chu discloses a process for the modification of readily prepared membranes by treating these membranes with an aqueous solution of an anionic charge modifying agent, (e.g. by immersing the membrane into this aqueous solution). This is in contrast to Nakabayashi which discloses a hollow fiber membrane spinning process in which an MPC copolymer is given to the inner filler (internal coagulate solution). The processes do not have anything in common with one another. Therefore, using Chu as a starting point, there is neither reason nor motivation for a person of ordinary skill in the art to conclude that adding a polyelectrolyte with negative fixed charges to the inner filler would result in a membrane with enhanced separation efficiency. Starting with Chu, it is far from routine for one skilled in the art to produce a membrane as described in claim 1 of the instant invention.

It is unclear to the Applicant how there may be a suggestion to improve the efficiency of the process by discharging a modifying agent in the inner lumen during production of the membrane, thereby reducing the number of steps

as is alleged by the Examiner. Applicant believes that whether or not such a suggestion exists, must first be judged by beginning from Chu. Even if it were the case that a reduction of the number of steps did occur, the change in the process resulting from adding the modifying agent to the "core liquid" instead of the solution of the film forming polymer in a solvent system (as is done by Chu) would result in membranes undesired by Chu. Chu seeks to produce membranes modified with a modifying agent which is bound to substantially all of the internal microstructure of the microporous membrane. (Column 5, Lines 39-45, Column 9, Lines 15-ff). This is important to Chu in order to solve the problems according to the invention of Chu, i.e. to have a decreased adsorptive capacity for anionic submicronic particulate due to the fact that these anionic particulates are often desirably retained in the liquid to be filtered. (Column 13, Lines 32-42). However, in order to have a reduced adsorptive capacity for anionic submicronic particulate, substantially all of the internal microstructure has to be modified.

When applying the process of Nakabayashi, only the surface of the membrane is modified which leaves the rest of the membrane structure intentionally unmodified. However, a membrane being modified in this manner does not have a decreased

adsorptive capacity. Therefore, even if there were a reduction of process steps, a person of ordinary skill in the art, if beginning from Chu's process, would never apply the process of Nakabayashi.

This leads the Applicant to question whether there is actually a reduction of process steps as is alleged by the Examiner. In the Applicant's opinion, the process of Chu and Nakabayashi are too different and cannot be compared by comparing the number of process steps. As previously mentioned, Chu discloses a process for the modification of readily prepared microporous membranes. (Column 11, Line 56 - Column 12, Line 3). This has the advantage of modifying e.g. all kinds of commercially available membranes in an after-treatment process. Nakabayashi, in contrast, related to processes during which formation of the membrane and formation of the modified surface occur simultaneously. Such a process in general is quite restricted with respect to the effective degrees of freedom to operate. Additionally, Nakabayashi regards these processes as being alternatives. (Page 2, Paragraph 15-16, Page 5, Paragraph 44).

The prior art reference or combination of references relied upon by the Examiner must teach or suggest all of the

limitations of the claims. See *In re Zurko*, 111 F.3d 887, 888-89, 42 U.S.P.Q.2d 1467, 1478 (Fed. Cir. 1997); *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970) ("All words in a claim must be considered in judging the patentability of that claim against the prior art."). The teachings or suggestions, as well as the expectation of success, must come from the prior art, not applicant's disclosure. See *In re Vaeck*, 947 F.2d 488, 493, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). In this instance, from the information detailed above, it is clear that Chu and Nakabayashi fail to teach or suggest all the limitations of Applicant's claims. Accordingly, Chu in view of Nakabayashi does not disclose all of the elements of claims 1 and 12. Therefore, this rejection must fail. Thus, claims 1 and 12 are not anticipated by Chu and Nakabayashi and should be allowed.

In reference to claims 2-11 and 14-16, dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious. *Hartness Int'l, Inc. v. Simplimatic Eng'g Co.*, 819 F.2d 1100, 1108, 2 USPQ2d 1826, 1831 (Fed. Cir. 1987); *In re Abele*, 684 F.2d 902, 910, 214 USPQ 682, 689 (CCPA 1982); see also *In re Sernaker*, 702 F.2d 989, 991, 217 USPQ 1, 3 (Fed. Cir. 1983). Thus, claims 2-11 and 14-16 are not

unpatentable over Chu in view of Nakabayashi and should be allowed.

Regarding added claims 17 and 18, Chu does not disclose membranes made from a hydrophobic synthetic polymer combined with a hydrophilic polymer, nor does Chu disclose methods for producing such membranes. Chu relates to skinless hydrophilic organic polymer microporous filter membranes modified with a charge modifying amount of an anionic charge modifying agent bonded to substantially all of the membrane microstructure (see Chu, Claim 1) whereby polyamide ("nylon") membranes, polyvinylidene fluorid membranes, cellulose acetate/-nitrate membranes are named as hydrophilic microporous membranes. (Column 6, Line 54 to Column 8, Line 68; Examples).

Additionally, Nakabayashi relates neither to membranes made from a hydrophobic synthetic polymer in combination with a hydrophilic polymer nor to methods for producing such membranes. The membranes of Nakabayashi are made from synthetic polymers only selected from the polymers listed in paragraph [13] of Nakabayashi without the addition of a hydrophobic polymer which accounts for hydrophilicity of the membrane. Nakabayashi indeed delimits from such membranes. (Page 1, Paragraphs 3-5).

Conclusion

In view of the foregoing, Applicant respectfully requests an early Notice of Allowance in this application.

Respectfully submitted,



Blake E. Vande Garde
Attorney for Applicant
Reg. No. 58,264

Customer No. 29494
Hammer & Associates, P.C.
3125 Springbank Lane
Suite G
Charlotte, NC 28226
Telephone: 704-927-0400
Facsimile: 704-927-0485
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